

may exempt a Federal or State agency from the provisions of the Act which regulate the manner in which a pesticide is made available for use or is used.

(b) *Organization.* (1) The provisions in subpart A of this part describe the four types of emergency exemptions authorized by the Agency and define terms used in this part.

(2) Subpart B of this part establishes procedures and criteria for specific, quarantine, and public health exemptions.

(3) Subpart C of this part establishes procedures and criteria for crisis exemptions.

#### § 166.2 Types of exemptions.

There are four types of emergency exemptions which may be authorized: specific, quarantine, public health, and crisis exemptions.

(a) *Specific exemption.* A specific exemption may be authorized in an emergency condition to avert:

- (1) A significant economic loss; or
- (2) A significant risk to:
  - (i) Endangered species,
  - (ii) Threatened species,
  - (iii) Beneficial organisms, or
  - (iv) The environment.

(b) *Quarantine exemption.* A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest new to or not theretofore known to be widely prevalent or distributed within and throughout the United States and its territories.

(c) *Public health exemption.* A public health exemption may be authorized in an emergency condition to control a pest that will cause a significant risk to human health.

(d) *Crisis exemption.* A crisis exemption may be utilized in an emergency condition when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption.

#### § 166.3 Definitions.

Terms used in this part shall have the meanings established by the Federal Insecticide, Fungicide, and Rodenticide Act. In addition, as used in

this part, the following terms shall also apply:

(a) The term *the Act* means the Federal, Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*

(b) The terms *the Agency* and *EPA* mean the U.S. Environmental Protection Agency.

(c) The term *beneficial organism* means any pollinating insect, or any pest predator, parasite, pathogen or other biological control agent which functions naturally or as part of an integrated pest management program to control another pest.

(d) The term *emergency condition* means an urgent, non-routine situation that requires the use of a pesticide(s) and shall be deemed to exist when:

(1) No effective pesticides are available under the Act that have labeled uses registered for control of the pest under the conditions of the emergency; and

(2) No economically or environmentally feasible alternative practices which provide adequate control are available; and

(3) The situation:

(i) Involves the introduction or dissemination of a pest new to or not theretofore known to be widely prevalent or distributed within or throughout the United States and its territories; or

(ii) Will present significant risks to human health; or

(iii) Will present significant risks to threatened or endangered species, beneficial organisms, or the environment; or

(iv) Will cause significant economic loss due to:

(A) An outbreak or an expected outbreak of a pest; or

(B) A change in plant growth or development caused by unusual environmental conditions where such change can be rectified by the use of a pesticide(s).

(e) The term *first food use* refers to the use of a pesticide on a food or in a manner which otherwise would be expected to result in residues in a food, if no permanent tolerance, exemption from the requirement of a tolerance, or food additive regulation for residues of

the pesticide on any food has been established for the pesticide under section 408 (d) or (e) or 409 of the Federal Food, Drug, and Cosmetic Act.

(f) The term *food* means any article used for food or drink for man or animals.

(g) The term *new chemical* means an active ingredient not contained in any currently registered pesticide.

(h) The term *significant economic loss* means that, under the emergency conditions: for a productive activity, the profitability would be substantially below the expected profitability for that activity; or, for other types of activities, where profits cannot be calculated, the value of public or private fixed assets would be substantially below the expected value for those assets. Only losses caused by the emergency conditions, specific to the impacted site, and specific to the geographic area affected by the emergency conditions are included. The contribution of obvious mismanagement to the loss will not be considered in determining loss. In evaluating the significance of an economic loss for productive activities, the Agency will consider whether the expected reduction in profitability exceeds what would be expected as a result of normal fluctuations over a number of years, and whether the loss would affect the long-term financial viability expected from the productive activity. In evaluating the significance of an economic loss for situations other than productive activities, the Agency will consider reasonable measures of expected loss.

(i) The term *Special Review* refers to any interim administrative review of the risks and benefits of the use of a pesticide conducted pursuant to the provisions of EPA's Rebuttable Presumption Against Registration rules, 40 CFR 162.11(a), or any subsequent version of those rules.

(j) The term *unreasonable adverse effects on the environment* means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

#### **§ 166.7 User notification; advertising.**

(a) A State or Federal agency that obtains an exemption may notify eligi-

ble users of the availability of the exempted pesticide(s) through user groups, retail dealers, and other means. Notification may include distributing copies of the section 18 approval letter, labeling, or other information to eligible persons.

(b) As set forth more fully in § 168.22 of this chapter, EPA interprets FIFRA sections 12(a)(1) (A) and (B) as making it unlawful for any person who distributes, sells, offers for sale, holds for sale, ships, delivers for shipment, or receives and (having so received) delivers or offers to deliver any pesticide, to advertise the pesticide for any use authorized by an emergency exemption, except for advertisements that are placed in media that address only persons in the geographical area to which the exemption applies, state the name and address of one or more retail dealers where users may buy the pesticide, and contain a prominent notice of the limitations on use under the emergency exemption. EPA may withdraw an exemption if the use of the pesticide covered by the exemption is advertised unlawfully.

[54 FR 1125, Jan. 11, 1989]

### **Subpart B—Specific, Quarantine, and Public Health Exemptions**

#### **§ 166.20 Application for a specific, quarantine, or public health exemption.**

(a) *General information required in an application for a specific, quarantine or public health exemption.* An application must be submitted in writing by the head of the Federal or State agency, the Governor of the State involved, or their official designee. If a designee has been delegated authority to request exemptions, written authorization of such delegation must accompany the request or be on file with the Agency. In addition, the application must contain all applicable information specified in paragraphs (a) (1) through (11) of this section.

(1) *Identity of contact persons.* (i) Unless otherwise specified, the person who submits the application will be considered the contact person for all matters relating to administration of the emergency exemption.